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Attorneys for Defendant Sandoz Inc.

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

OTSUKA PHARMACEUTICAL CO., LTD.,	:	
	:	Civil Action No.
Plaintiffs,	:	3:07-cv-01000-MLC-JJH
	:	
v.	:	
	:	
SANDOZ INC.,	:	
	:	
Defendant.	:	
	:	

**DEFENDANT SANDOZ INC.'S ANSWER, AFFIRMATIVE DEFENSES AND
COUNTERCLAIMS**

Defendant, Sandoz Inc. (“Sandoz”) by counsel, as for its answers to the Complaint of Plaintiff Otsuka Pharmaceutical Co., Ltd. (hereinafter referred to as “Otsuka”) states and alleges as follows:

Answering the allegations of the specific paragraphs of the Complaint, Sandoz responds as follows:

1. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations and therefore denies the allegations of paragraph 1.
2. Sandoz admits that it is a corporation organized under the laws of the State of Colorado and has a place of business located at 506 Carnegie Center, Princeton, NJ 08540-6543, and denies the remaining allegations of paragraph 2.
3. Sandoz admits that this paragraph purports to state a cause of action against Sandoz for patent infringement arising under the Patent Laws of the United States, Title 35, United States Code, §100 *et seq.*, including 35 U.S.C. §§ 271 and 281.
4. Sandoz admits the allegations of paragraph 4.
5. Sandoz admits this Court has personal jurisdiction over Sandoz for the purposes of this action, and denies the remaining allegations of paragraph 5.
6. Sandoz admits the allegations of paragraph 6.
7. Sandoz admits that a copy of the ‘528 patent is attached as Exhibit A, but lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 7 and therefore denies those allegations.
8. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations and therefore denies the allegations of paragraph 8.

9. Sandoz admits that a copy of a Patent Term Extension for the '528 patent is attached as Exhibit B, but lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 9 and therefore denies those allegations.

10. Sandoz admits that a copy of a Reexamination Certificate for the '528 patent is attached as Exhibit C, but lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 10 and therefore denies those allegations.

11. Sandoz admits the allegations of paragraph 11.

12. Sandoz admits that the '528 patent is listed in the Orange Book, but lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 12 and therefore denies those allegations.

13. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations and therefore denies the allegations of paragraph 13.

14. Sandoz admits the allegations of paragraph 14.

15. Sandoz admits the allegations of paragraph 15.

16. Sandoz admits that, on January 29, 2007, Sandoz sent to Otsuka a Notice of Patent Certification under 21 U.S.C. §355(j)(2)(B)(i) and/or (ii) and 21 C.F.R. §314.95(c), but lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 16 and therefore denies those allegations.

17. Sandoz denies the allegations of paragraph 17.

18. Sandoz denies the allegations of paragraph 18.

19. Sandoz denies the allegations of paragraph 19.

Sandoz denies that Plaintiff is entitled to the relief requested in the Complaint.

AFFIRMATIVE DEFENSES

20. Sandoz has not and does not infringe any valid and enforceable claims of U.S. Patent No. 5,006,528.

21. Sandoz has not, does not and will not induce or contribute to any infringement of any claim of U.S. Patent No. 5,006,528 and is not liable for any act that would be held to be any act of infringement of the '528 patent.

22. Upon information and belief, the claims of U.S. Patent No. 5,006,528 are invalid under one or more provisions of 35 U.S.C. § 1, *et seq.*, including but not limited to, §§ 102, 103 and 112.

23. Upon information and belief, the claims of U.S. Patent No. 5,006,528 are unenforceable on the grounds of inequitable conduct in the prosecution of the original application for and/or reexamination of the '528 patent in the United States Patent and Trademark Office.

24. Upon information and belief, the claims of U.S. Patent No. 5,006,528 are unenforceable on the grounds of patent misuse.

25. Upon information and belief, the claims of U.S. Patent No. 5,006,528 are unenforceable on the grounds of prosecution laches.

26. Upon information and belief, no damages may be received by Plaintiff pursuant to one or more provisions of 35 U.S.C. § 1, *et seq.*, including, but not limited to §§ 286 and 287.

27. Plaintiff has not suffered any damages.
28. Plaintiff is not suffering an irreparable injury.
29. Sandoz reserves the right to assert such other defenses as may appear as discovery proceeds in this case.

COUNTERCLAIMS

30. Sandoz counterclaims against Plaintiff pursuant to the patent laws of the United States, 35 U.S.C. § 1, *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §2201, *et seq.*

31. These counterclaims arise out of the same transactions and occurrences that are the subject of the claims asserted in the Complaint in the above-captioned action. Jurisdiction in this Court is proper pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202 and Rule 13 of the Federal Rules of Civil Procedure.

32. Plaintiff, having brought suit against Sandoz, has submitted itself to the jurisdiction of this Court. Venue in this Court is proper pursuant to 28 U.S.C. § 1391(c).

First Counterclaim – Declaration of Unenforceability

33. Upon information and belief, U.S. Patent Application No. 07/424,719 (“the ‘719 application”) is the application that resulted in the ‘528 patent attached as Exhibit A to the Complaint.

34. During the prosecution of the '719 application, Plaintiff had a duty to disclose to the U.S. Patent and Trademark Office ("PTO") all information known to Plaintiff to be material to patentability pursuant to 37 C.F.R. § 1.56.

35. The following prior art references were material to the patentability of one or more claims of the '719 application:

- a) U.S. Patent Nos. 4,734,416 and 4,824,840;
- b) German Patent No. 2,912,105;
- c) U.S. Patent No. 4,914,094 and European Patent No. 0 226 441;
- d) U.S. Patent No. 4,234,584;
- e) Japanese Patent No. 56-49361;
- f) Banno et al., "Studies of 2(1H)-Quinolinone Derivatives as Neuroleptic Agents, I, Synthesis and Biological Activities of (4-Phenyl-1-piperazinyloxy)-2(1H)-quinolinone Derivatives," Chem. Pharm. Bull., Vol. 36, No. 11, pp. 4377-4388 (Nov. 25, 1988) ("the Banno article").

36. Upon information and belief, Plaintiff was aware of all the prior art references listed in Paragraph 35 during the prosecution of the '719 application, and further, was aware of the materiality of those references.

37. Upon information and belief, Plaintiff failed to submit an Information Disclosure Statement containing, or otherwise provide the PTO with copies of, any of the prior art references listed in Paragraph 35 during the prosecution of the '719 application.

38. Upon information and belief, Plaintiff failed to disclose the existence of the Banno article during the prosecution of the '719 application.

39. Plaintiff misidentified German Patent No. 2,912,105 in specification of the '719 application.

40. Upon information and belief, Plaintiff mischaracterized the relative materiality of the prior art references referenced in the '719 application and of which no copies were provided to the PTO. In particular, the '719 application, when discussing the prior art, listed three tiers of prior art references: Tier 1, which included U.S. Patent No. 4,734,416 and German Patent No. 2,912,105, which were stated to disclose only generic structural formulae; Tier 2, which were stated to disclose chemical structural formulae similar to that of carbostyryl derivatives of the claimed compounds, but having different pharmacological activities; and Tier 3, which were stated to disclose chemical structural formulae similar to those of the carbostyryl derivatives of the claimed compounds and having similar pharmacological activities.

41. The Patent Examiner examining the '719 application cited several compounds disclosed in U.S. Patent No. 4,824,840, which is in the same patent family as U.S. Patent Nos. 4,734,416 and German Patent No. 2,912,105, as prior art rendering certain claims of the '719 application unpatentable.

42. U.S. Patent Nos. 4,734,416 and 4,824,840 do not disclose all of the chemical compounds disclosed in German Patent No. 2,912,105 and the Banno article.

43. Upon information and belief, when Plaintiff argued for the patentability of the claims of the '719 application over U.S. Patent No. 4,824,840 during the prosecution of the '719 application, Plaintiff did not disclose to the Patent Examiner that German Patent No. 2,912,105 and the Banno article disclose compounds that are closer to certain

claims of the '719 application than the compounds disclosed in U.S. Patent Nos. 4,734,416 and 4,824,840.

44. Plaintiff submitted declarations in support of its arguments for the patentability of the claims of the '528 patent. In particular, Plaintiff submitted:

a) a declaration by Yasuo Oshiro (the "Oshiro Declaration"), which stated that certain claimed compounds yielded unexpected results sufficient to overcome the Patent Examiner's rejections finding the claims of the '719 application unpatentable during prosecution of the '719 application; and

b) a declaration by Tsuyoshi Hirose (the "Hirose Declaration"), which stated that certain claimed compounds yielded unexpected results sufficient to overcome the Patent Examiner's rejections finding the claims of the '528 patent unpatentable during reexamination of the '528 patent.

45. In order for the Oshiro and Hirose Declarations to be effective for overcoming the rejections finding the claims of the '719 application and the '528 patent unpatentable, Plaintiff was required to compare the closest prior art to the claimed compounds.

46. German Patent No. 2,912,105 and the Banno article recite compounds that are closer to certain claims of the '719 application than any of the compounds disclosed in U.S. Patent No. 4,824,840.

47. Upon information and belief, Plaintiff knew that German Patent No. 2,912,105 and the Banno article recite compounds that are closer to certain claims of the '719 application than any of the compounds disclosed in U.S. Patent No. 4,824,840

during the prosecution of the '719 application because, *inter alia*, Yasuo Oshiro is a named inventor of U.S. Patent No. 4,824,840 and German Patent No. 2,912,105, and is a listed author of the Banno article.

48. Upon information and belief, the Oshiro and Hirose Declarations are improper and insufficient to establish unexpected results.

49. Upon information and belief, Plaintiff failed to disclose material prior art, affirmatively misrepresented material facts, and/or submitted false and misleading information, with intent to deceive the PTO, by failing to disclose any of the known material references listed in Paragraph 35 in accordance with Plaintiff's duty of disclosure pursuant to the requirements of the PTO, not disclosing the existence of the Banno article, misidentifying German Patent No. 2,912,105 in the specification of the '719 application, affirmatively mischaracterizing the materiality of German Patent No. 2,912,105 relative to other prior art patents in the specification of the '719 application, failing to inform the Patent Examiner when the Examiner cited U.S. Patent No. 4,824,840 that its related German Patent No. 2,912,105 and the Banno article disclosed compounds that are closer to certain claims of the '719 application than the compounds disclosed in the '840 patent, submitting declarations for the purpose of establishing unexpected results that did not compare the closest prior art to the claimed compounds, and submitting improper and insufficient declarations for the purpose of establishing unexpected results.

Second Counterclaim – Declaration of Invalidity

50. U.S. Patent No. 5,006,528 is invalid for failing to comply with the requirements of the patent laws of the United States, 35 U.S.C. § 1, *et seq.*, including but not limited to, §§ 102, 103 and 112.

Third Counterclaim – Declaration of Noninfringement

51. Sandoz has not infringed, is not infringing, and will not infringe any valid and enforceable claim of U.S. Patent No. 5,006,528 and is not liable for any act of infringement of the '528 patent.

WHEREFORE, Sandoz seeks judgment against Plaintiff as follows:

- A. That Plaintiff's Complaint, and all of its causes of action, be dismissed with prejudice;
- B. That judgment be entered in favor of Sandoz, including an Order adjudging U.S. Patent No. 5,006,528 unenforceable, invalid, and not infringed by Sandoz;
- C. That Sandoz be awarded its attorneys' fees and costs pursuant to 35 U.S.C. §285; and
- D. That Sandoz be awarded such other and further relief as the Court deems just and proper.

Respectfully submitted,

HILL WALLACK LLP

Attorneys for Defendant Sandoz Inc.

Dated: April 20, 2007

By: s/Eric I. Abraham

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CERTIFICATE OF SERVICE

This is to certify that a true and correct copy of the foregoing **DEFENDANT SANDOZ INC.'S ANSWER, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS** is to be electronically filed. Notice of this filing will be sent to all parties by operation of the Court's electronic filing system. Parties may access this filing through the Court's system.

Date April 20, 2007

s/Eric I. Abraham
Eric I. Abraham

LOCAL CIVIL RULE 11.2 CERTIFICATION

I hereby certify pursuant to Local Civil Rule 11.2 that to the best of my knowledge, information and belief the matter controversy is not the subject of any other proceeding or action pending in any court or pending in any arbitration or administrative proceeding.

I certify that the foregoing statements made by me are true. I am aware that if any of the foregoing statements made by me are willfully false, I am subject to punishment.

Executed on April 20, 2007.

s/Eric I. Abraham
ERIC I. ABRAHAM

F.R.C.P. RULE 7.1 DISCLOSURE STATEMENT

ERIC I. ABRAHAM, of full age, under oath, hereby declares as follows:

1. I am a member of the Bar of the State of New Jersey and am admitted to practice before the United States District Court for the District of New Jersey.
2. I represent Defendant Sandoz Inc.
3. Sandoz Inc. is wholly owned by Novartis Pharmaceuticals Corp. of East Hanover, New Jersey.
4. Novartis Pharmaceuticals Corp. is wholly owned by Novartis Corporation of New York, New York.
5. Novartis Corporation is wholly owned by Novartis AG, which is publicly traded under the symbol NVS.

I declare that the foregoing statements made by me are true. I am aware that if any of the foregoing statements made by me are willfully false, I am subject to punishment.

Executed on April 20, 2007.

s/Eric I. Abraham
ERIC I. ABRAHAM